

11 May 1999 (119 () *99 MAY 14 P2:13

Dockets Management Branch (HFA-305) Docket #98N-1265 Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Dear People:

I oppose the Draft MOU being proposed by the FDA. In particular, I object to the definition of "inordinate amount" restricting the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Here is my story. I am 57 years old. I own and run a management consulting business. I am now almost 2 years post-menopausal. Were it not for my doctor being able to work with the Madison Pharmacy in Wisconsin, I would be limited to "one size fits all" Premarin. I would gain weight, feel bloated, experience significant breast soreness, etc. I'm told that about 75% of post-menopausal women stop HRT within a year. If you experienced the above symptoms, I bet you would, too.

I experience none of these symptoms with HRT tailored specifically to the doses I need based on periodic saliva tests. Instead, I am in a state of high productivity in my career and my life, slim and empowered and mentally alert and alive. The difference is so profound you would probably drive me to illegal activities if you made it illegal to ship sufficient quantities of these medications across state lines.

Please recognize the rights of US citizens, with our doctors, to manage our health wisely. Please call or e-mail me for further comments.

Most sincerely,

Kaye M. Shackford

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Better bargaining with the thirty of the transfer of the trans



By J.A. Donoghue

Interest-based negotiating improves both the efficiency of the process and the quality of the outcome

he airline industry is entering a potentially hazardous period of labor contract negotiations. The need to find mutually agreeable solu-

tions in a way that builds future relations between labor and management is an important consideration that should not must not—get lost in the push to conclude a deal.

As ATW described the situation last month (2/99, p. 33), labor groups are looking for a payback from companies flush with profits, while airlines, remembering the rich contracts of the late 1980s that contributed to the impact of the recession, are justifiably cautious about opening the benefit spigot too wide.

For carriers in the U.S., the result of this process so far has been a couple of strikes and several near-strikes brought about by a failure of negotiations, plus a general feeling of rancor.

Management interests in seeking a positive conclusion to negotiations were amply illustrated last month when American Airlines was hit by a pilot sick-out that canceled thousands of flights. The ill will lingering from the contentious negotiations and strike two years ago festered to the point that the relatively insignificant acquisition of Reno Air and American's integration plan triggered the Allied Pilots Association reaction.

This ill will can be linked directly to the ageold approach that views a negotiation as a process in which one side must come out victorious over the other, one position must prevail.

The idea that there is an alternative, a different way to approach negotiations as a meeting of people with many common interests and a few conflicts that can be resolved through a mutually creative process, can be categorized easily as an exercise in touchy-feely, not deserving of consideration in a hard-edged business world.

And yet, just such an idea is gaining mainstream acceptance. This approach is decidedly not from the soft-position school of negotiation. It uses brainpower and an emphasis on clear communication to focus on each party's interests in the negotiation. Interest-based bargaining has been used in numerous industry negotiations, has been embraced by U.S. National Mediation Board chairwoman Magdalena Jacobsen and is being endorsed actively by a number of aviation and aerospace companies as the way to do business in general. American's flight attendants and managers are preparing for talks by training in interest-based bargaining techniques.

Developed more than two decades by the very unsoft school of Harvard and its Harvard Negotiation Project, the interest-based bargaining approach was first detailed by Roger Fisher and William Ury in the book "Getting to Yes."

Chief practitioner of this craft to the aviation industry is The Mattford Group through a series of workshops held around the U.S. and now beginning to attract overseas participants. Via a rigorous five-day negotiation "boot camp" that pushes people to learn the wide array of tools available to a sophisticated negotiator, instructors Kaye and Joe Shackford try to show their students not only how to improve the negotiation process but also how to improve the quality of the outcome.

By no means does interest-based negotiation equate to simply giving in to the other position. Each party has to protect its own interests and, in doing so, sometimes the process doesn't work. But even in those experiences, an interest-based approach and good preparation work still will give the best possible outcome.

Workshop attendees learn not only negotiating tools but also the importance of clear communication and trust. Ultimately, trust is the key to the success of interest-based bargaining because it requires the disclosure of far more information than the close-to-the-vest style of hard-position bargaining, a willingness to communicate a fuller picture of desired outcomes and range of acceptable options to the negotiating "partner."

At the end of the day airlines will be better businesses if their relations with labor groups—and suppliers as well—can be based on agreements derived through interest-based negotiations. Airlines should jump at the chance to embrace the decades of experience built up in this process and use it to build quality agreements that will survive the next downturn intact. An unhappy work force or a too-generous contract are not baggage to take into a downturn.

The MATTFORD Group





